Department of Energy
Fermi Site Office
Post Office Box 2000
Batavia, Illinois 60510

NOV 27 2009

Dr. Bruce L. Chrisman
Chief Operating Officer
Fermilab
P.O. Box 500
Batavia, Illinois 60510

Dear Dr. Chrisman:

SUBJECT: FERMI SITE OFFICE (FSO) ASSESSMENT PLAN REVIEW OF THE FERMI NATIONAL ACCELERATOR LABORATORY (FERMILAB) INTEGRATED QUALITY ASSURANCE (IQA) PROGRAM REPORT

Reference: Letter, J. Livengood to B. Chrisman, dated July 2009, Subject: Same As Above

Enclosed is the subject report for your use. The FSO Assessment Plan review of Fermilab's Quality Assurance (QA) program was led by John Adachi from the Department of Energy Office of Science (SC) Chicago (CH) Integrated Support Center (ISC) and an assessment team composed of representatives from SC, SC-CH-ISC, New Brunswick Laboratory, and other SC laboratories. The on-site portion of the assessment was conducted September 14-18, 2009.

The purpose of this QA assessment is twofold: (a) to evaluate whether the documented program adequately addresses the requirements of DOE O 414.1C including its Contractor Requirements Document (CRD), and (b) to status the level of QA program implementation. FSO charged the Assessment Team with evaluating Fermilab's efforts to implement QA across the Laboratory even though Laboratory-wide and organization-specific procedures were not fully developed. The report defines potentially adverse issues as 'concerns'. The review resulted in one significant concern relating to the adequacy of the draft engineering manual contents.

Please prepare a corrective action plan (CAP) to address each of the concerns in the report and submit to our office by January 15, 2010. A brief statement on the deliverables is to be provided for each action as well as a corresponding completion date. The Assessment Team restated some reoccurring concerns that have been open since the 2006 DOE FSO QA review. The Laboratory should also include with the CAP, the status, summary, and planned completion dates for actions occurring to address the concerns of less than adequate QA implementation from the 2006 DOE FSO QA review. Also provide a current project plan with the CAP. FSO requests a meeting to reach mutual agreement on proposed corrective actions prior to the formal submittal. Upon receipt of the action plan, FSO will reference your project plan revisions to assess progress against the CAP.

As always, we appreciate every participant's cooperation in working with the Assessment Team to complete this review.

If you have any questions, please contact Berline Short or John Scott at extensions 4197 and 2250 respectively.

Sincerely,

Mark Bollinger, Acting
Site Manager

Enclosure:
As Stated

cc: P. Oddone, w/encl.
Y. - K. Kim, w/encl.
R. Grant, w/encl.

U.S. DEPARTMENT OF ENERGY

OFFICE OF SCIENCE – FERMI SITE OFFICE

ASSESSMENT OF FERMI NATIONAL ACCELERATOR LABORATORY QUALITY ASSURANCE PROGRAM

Purpose of Assessment:

The purpose of this assessment was to evaluate the efforts of Fermi National Accelerator Laboratory (a.k.a. Fermilab) to develop and implement a Quality Assurance (QA) program that satisfies the requirements of the Department of Energy (DOE) QA Directive [DOE O 414.1C, *Quality Assurance*].

In 1995, the DOE Office of Science (SC) line management removed the DOE QA Directive from the Fermilab contract through the application of the Necessary & Sufficient (N&S) process [later referred to as the Work Smart Standards (WSS) process]. In 2006, under the direction of a new manager, the Fermi Site Office (FSO) sponsored a review to ascertain the status of QA implementation at Fermilab. That review identified numerous concerns of less than adequate QA implementation. In the decade between the removal of the DOE QA Directive from the Fermilab contract in 1995 and the QA review in 2006, without the contractually imposed DOE QA Directive or a national or international QA consensus standard to serve as a requirements baseline, the quality assurance program at Fermilab had declined.

The DOE Fermi Site Office included the DOE QA Directive in the new Fermilab contract that went into effect at the beginning of 2007. Since the effective date of the current contract, Fermilab has undertaken an extensive effort to develop and implement a QA program that addresses the requirements of DOE O 414.1C. The Fermilab Integrated Quality Assurance Program (IQA) was approved by FSO in November 2008. The design of the Fermilab IQA has many sections of the IQA program supported by Laboratory-wide procedures; while other parts of the IQA program allow for organization-specific procedures/processes to be developed, maintained, and implemented at the Division/Section/Center (D/S/C) level. Fermilab is using project management tools to manage the efforts to institute the IQA throughout the Laboratory. Fermilab has planned activities to institute the IQA across the laboratory scheduled into 2011.

While it is understood that Fermilab has not yet developed and implemented all of the Laboratory-wide and D/S/C level procedures, and therefore has not yet achieved full implementation of the IQA, FSO deemed it appropriate to sponsor this assessment to evaluate the status of Fermilab's efforts to institute QA across the Laboratory.

Assessment Scope:

FSO employed the services of the Safety and Technical Services (STS) Division of the DOE SC Chicago Office (CH) of the DOE SC Integrated Support Center (ISC) to plan, staff, lead and perform this assessment of the Fermilab IQA program. The assessment scope was established by FSO. The on-site investigative portion of the assessment was conducted during the period of September 14-18, 2009.

The assessment scope included the Fermilab IQA and associated procedures that address the following requirements of the Contractor Requirements Document of DOE O 414.1C, *Quality Assurance*:

- Criterion 1 - Program

- Criterion 2 - Personnel Training & Qualification
- Criterion 3 - Quality Improvement
- Criterion 4 - Documents and Records
- Criterion 5 - Work Processes
- Criterion 6 - Design
- Criterion 7 - Procurement
- Criterion 8 - Inspection and Acceptance Testing
- Criterion 9 - Management Assessment
- Criterion 10 - Independent Assessment
- Section 4 - Suspect/Counterfeit Items Prevention

The following Fermilab Divisions/Sections/Centers were sampled for this assessment:

- Particle Physics Division (PPD)
- Computing Division (CD)
- Business Services Section (BSS)
- Facilities Engineering Services Section (FESS)
- Workforce Development & Resources Section (WDRS)
- Accelerator Division (AD)
- Technical Division (TD)
- Office of Quality & Best Practices (OQBP)
- Environment, Safety and Health Section (ES&HS)

Approach:

The QA assessment team was comprised of persons from several SC laboratories, SC-headquarters, and SC-ISC-CH. The assessment team members were:

- John Adachi, SC-CH-STS – Assessment Team Leader
- Karl Moro, SC-CH-STS
- Tom McDermott, SC-CH-STS
- Tracy Sims, SC-CH-STS
- Matt Cole, SC-31.1
- Margaret Legel, New Brunswick Laboratory
- Robert Arthurs, Argonne National Laboratory
- Judy Malsbury, Princeton Plasma Physics Laboratory
- Jessie Wilke, Brookhaven National Laboratory

The Head of the Fermilab Office of Quality and Best Practices (OQBP) served as the primary point-of-contact for the assessment team leader. The OQBP QA Manager and QA Engineers (QAE) served as points-of-contact for the assessment team members. The D/S/C QA Representatives (QAR) assisted the assessment team members by scheduling and coordinating assessment interviews of persons from their D/S/C.

Criteria and Review Approach Documents (CRADs) were developed to aid the team in the performance of the assessment. The CRADs contain the criteria against which the Laboratory was assessed. The CRADs also contain supplemental lines-of-inquiry that served as aids to the assessors. The CRADs were provided to Fermilab approximately one month prior to the on-site investigative portion of the assessment. Fermilab provided to the assessment team the documents and records they felt demonstrated how the IQA and its supporting documents satisfy the DOE QA criteria. The assessment team reviewed applicable documents and records, and interviewed cognizant Fermilab managers and staff, to gather information that enabled the team to evaluate the adequacy of the Fermilab IQA program.

During the on-site portion of the assessment, the assessment team leader provided FSO and Fermilab OQBP with daily briefings on the status of the assessment. Developing issues/concerns were conveyed to the Laboratory as they surfaced in order to maintain an open "no surprises" approach to performing the assessment.

Because of the focus of the assessment, i.e., to evaluate the efforts of Fermilab to institute the newly developed IQA throughout the Laboratory, the assessment team was often evaluating documents still in draft, corrective action efforts still in progress, and processes not yet fully implemented. This did not lend itself to categorization of issues identified during the assessment using the traditional assessment terminology of "findings", as citing a finding against programs/processes still under development does not fit the definition of "finding". Therefore, this report identifies potentially adverse issues as "concerns" or "significant concerns". Positive conditions identified through the assessment are identified as "strengths" and "noteworthy practices".

Executive Summary:

Since the current Fermilab contract went into effect at the beginning of 2007, the Laboratory has embarked upon a comprehensive effort to institute its Integrated Quality Assurance program throughout all elements of the Laboratory. These efforts are scheduled to yield a fully implemented IQA by the end of 2011. Fermilab has brought the expertise of QA professionals into this effort through its industrial partner EG&G. The Laboratory's approach to developing and implementing the IQA embodies the recognition that to achieve a fully implemented and effective QA program, buy-in for the IQA must be achieved in every D/S/C and at all levels of the organization.

The involvement of the Laboratory Director in communicating to the entire Fermilab population the importance and benefits of the IQA is particularly noteworthy.

This assessment cited one significant concern: the draft *Fermi National Accelerator Laboratory Engineering Manual*, Revision 0.2, does not provide sufficient detail and rigor to effectively implement DOE O 414.1C, *Quality Assurance* Criterion 6 *Design*, the Fermilab *Integrated Quality Assurance* program Chapter Six *Design*, and the recommendations of the Fermilab *Root Cause Analysis for the Large Hadron Collider Magnet System Failure* report.

It is the conclusion of the assessment team that with continued management support for the Laboratory's initiative to implement the IQA program, Fermilab can be successful in their efforts to achieve acceptable implementation of the DOE QA requirements.

The subsequent sections of this report present discussion of the results of the assessment. Numerous strengths and concerns were identified; they are detailed in the following sections of the report.

Results:

CRITERION 1 – PROGRAM

Discussion:

The contract [DE-AC02-07CH11359] between the Department of Energy (DOE) and Fermi Research Alliance (FRA), which went into effect in January 2007, requires the Fermi National Accelerator Laboratory (Fermilab) to implement the DOE quality assurance requirements of DOE O 414.1C, *Quality Assurance*. Consistent with DOE O 414.1C, Fermilab has elected to use American National Standards Institute/American Society for Quality Z1.13-1999, *Quality Guidelines for Research*, to address the quality of its scientific activities.

To assist in meeting these new contractual requirements, FRA contracted with EG&G to provide the Laboratory with technical assistance for implementing a quality assurance program. EG&G QA professionals have been assigned to work as part of the Laboratory's quality organization. EG&G has since established a project plan, has initiated that project plan, and has scheduled implementation of the project plan through fiscal year 2011. If implemented as planned this approach should ensure the establishment of a comprehensive and effective Laboratory-wide quality assurance program.

Chapter 10 of the *Director's Policy Manual* designates the Head of the Fermilab Office of Quality and Best Practices (OQBP) as the senior Laboratory official responsible for the development, implementation, assessment, and improvement of the IQA. The OQBP Head reports directly to the Laboratory Director and advises the Laboratory's Directorate on matters pertaining to quality assurance. OQBP is supported by 16 employees of EG&G, which includes 4 Quality Assurance Engineer (QAE) positions. The hiring of 2 additional EG&G QAEs has been proposed.

Chapter 10, *Quality Assurance*, of the *Director's Policy Manual*, establishes the foundation of the Fermilab IQA. The IQA is intended to provide a single, integrated approach for assuring quality throughout Fermilab. The IQA establishes Laboratory-wide QA expectations to be implemented by all of the Fermilab D/S/Cs.

The Fermilab Director is actively engaged in communicating to the entire Laboratory staff the importance of the IQA to all aspects of work – research as well as operations - at Fermilab. Such communication by the Director has been through the Fermilab newsletter, the Director's "all-hands" meetings, memoranda to laboratory staff, and various other forums. It is apparent from review of these communications, and interviews during this assessment, that the Laboratory Director understands the benefits that an appropriately designed QA program can bring to Fermilab, and that he is taking a leadership role in the Laboratory's efforts to fully implement the IQA.

The IQA is composed of a document hierarchy that starts with the IQA program description document (IQA 1001, *Integrated Quality Assurance*) which is aligned with the 10 QA criteria of DOE O 414.1C, programmatic implementing procedures, and D/S/C implementing procedures. The most recent revision of the IQA 1001 was issued by the Laboratory on October 23, 2008, and approved by the DOE Fermi Site Office on November 5, 2008.

Line management is responsible for implementing the expectations set forth by the IQA. Each D/S/C has an assigned Quality Assurance Representative (QAR) to assist their

respective management with implementing QA. Of the ten QARs, nine serve in this capacity as a collateral-duty. Each QAR is supported by an appointed EG&G QAE. QARs were selected by their organizations and attended a series of orientation and training sessions to prepare them for supporting implementation of the IQA and the Fermilab Integrated Contractor Assurance Program (FICAP).

During the Spring of 2009 in collaboration with the OQBP QAEs, the D/S/C QARs conducted "As-Is" assessments of D/S/C-level work processes covering all DOE 414.1C requirements with special emphasis given to documents and records, item control, control of measuring and test equipment, and qualification and training. These assessments were to give Fermilab management a baseline understanding of the extent of current implementation of its contractual QA commitments.

The assessments concluded that most of the IQA and FICAP requirements are being met. When gaps were identified between the "as-is" and "to-be" states, corrective action plans were developed by the impacted D/S/C. OQBP evaluated each D/S/C corrective action, to identify Laboratory-wide cross-cutting issues that merited elevated attention. OQBP established 23 such "elevated" laboratory-wide corrective action plans (CAPs). In addition, the Fermilab As-Is QA baseline assessment identified 21 of 26 "less than adequate" issues from the previous 2006 DOE assessment of Fermilab's QA Program are closed and have been verified. The remaining five "less than adequate" issues that are still open are being managed as part of the Fermilab CAP process. It was reported during interviews that many of the organizational-specific corrective actions have been completed, or were near completion.

IQA implementation within each D/S/C was found to vary. Because of its recent roll-out, Laboratory-wide IQA implementation is relatively limited. For many years the Technical Division has had a well established QA program. Also, because of the traditional business-related practices characteristic of the nature of their work, the CD and BSS were already ahead of the other D/S/C at implementing the QA practices called for in the IQA.

Fermilab has already achieved management system certification with International Organization for Standardization (ISO) 14001, *Environmental Management System*, and Occupational Health and Safety Assessment Series 18001, *Occupational Health and Safety Management Systems*. In addition, the Laboratory's Computing Division is now pursuing certification with ISO/International Electrotechnical Commission 20000, *Information Technology Service Management*.

Conclusion:

The Fermilab IQA has been approved by the Laboratory Director and the Fermi Site Office. The IQA establishes the Laboratory's expectations for satisfying the DOE QA requirements set forth in DOE O 414.1C which are contractually imposed through the FRA contract with DOE. The Fermilab Director has taken an active role in communicating the importance of the IQA to the entire Laboratory staff. The IQA is overseen by the OQBP. The OQBP Head reports directly to the Laboratory Director and advises the Laboratory Directorate on matters pertaining to QA. The IQA is supported by a cadre of OQBP QA professionals supporting D/S/C QARs responsible for monitoring IQA implementation within their respective organization. The implementation status of IQA requirements has recently been determined and corrective action to resolve gaps have been established. Fermilab has achieved additional environment, safety and health management system certifications, and is in pursuit of another for information technology service management.

Strength:

- Fermilab is applying project management discipline to their efforts to develop and implement the IQA program throughout the Laboratory; this is demonstrated by their

utilization of a project plan to manage the implementation of the Laboratory-wide IQA program.

Noteworthy Practice:

- The Fermilab Director has taken an active role in communicating the importance of the IQA to the entire Laboratory staff.

CRITERION 2 - PERSONNEL TRAINING & QUALIFICATION

Discussion:

Chapter 19, *Training*, of the *Director's Policy Manual* states that Fermi National Accelerator Laboratory (Fermilab) is to ensure all necessary training has been provided to employees and any others performing work at the Laboratory, that mandatory training gets reported by the training organization, that training records are maintained in a central database, that work not be performed unless required training has been completed, that line management is responsible for developing training plans for their employees, and their employees are receiving their required training. Chapter 19 continues by noting that the "Training and Development Department, a part of Laboratory Services" will begin the transition of accepting responsibility for all training records and training databases. There is currently no "Training and Development Department, a part of Laboratory Services" organization. The Workforce Development Resources Section (WDRS) "As-Is" assessment recognized the inaccurate organization reference, and the actions called out by Chapter 19 were not occurring as intended. Because these gaps have Laboratory-wide implications, an elevated corrective action plan (OQ-06/09/2009-1) was eventually prepared to make the necessary revision of Chapter 19. CAP OQ-06/09/2009-1 shows changes to Chapter 19 to include defining the current organizational structure of the Laboratory and associated responsibilities.

CAP OQ-06/09/2009-1 notes that the WDRS Office for Professional and Organization Development will communicate all required training, including job-specific training, and assure that it is entered into the TRAIN database. This, along with open items from the 2006 DOE review of Fermilab's QA Program, led to preparation of an elevated corrective action plan (OQ-08/10/2009-1) calling for the WDRS Office for Professional and Organization Development to propose a process for tracking on-the-job training in TRAIN by means of an employee's Individual Training Needs Assessment (ITNA).

The status of CAP OQ-06/09/2009-1 indicates it to be on track to meet its estimated completion date of October 15, 2009. Likewise, the status of CAP OQ-08/10/2009-1 indicates it to be on track to meet its estimated completion date of January 1, 2010. These corrective actions are considered to be appropriate for establishing a Laboratory-wide training and qualification program.

Training and qualification at Fermilab is currently managed through the TRAIN database. TRAIN is used to document courses taken, training needs, course attendance, and qualifications. Though TRAIN is owned by the ES&HS and originally intended for safety purposes, it is being used increasingly more to capture any training, e.g., security, cyber, business management, and records management.

Concerns about the expanded use of TRAIN beyond safety and the potential conflict between ES&HS priorities and ES&HS management of non-safety training was discussed with Fermilab's Chief Operating Officer. He acknowledged the potential for this conflict and stated that this is an area in need of review and revision (as reflected by corrective action OQ-06/09/2009-1).

Fermilab Environment, Safety and Health Manual (FESHM) 4010, *Environment Safety and Health Training*, details responsibilities and requirements for the management of training and qualification currently practiced at the Laboratory. FESHM 4010 requires supervisors to prepare an ITNA for each new employee, and to review/revise ITNAs annually or whenever changes in job assignments and/or hazard exposures occur. The ITNA form includes a series of questions related to the duties an employee is to perform. These questions are linked to one or more training courses in TRAIN. The completed ITNA results in creation of an Individual Training Plan (ITP). The ITNA and ITP are then integrated with TRAIN.

Through TRAIN all initial and recurrent training is tracked. TRAIN provides electronic notification to employees and their supervisor of scheduled courses, training coming due, training missed, and training completed.

FSO has established a training related performance measure for Fermilab through the Performance Evaluation and Measurement Plan. This measure calls for safety-related training for line managers and staff to be well-defined, and required training be identified in ITNAs for all managers and staff. Targets for this measure requires that completion of ITNAs for all employees is ensured and tracked; completion of required training for all employees is tracked and status is discussed at senior manager's meetings; and safety training is periodically reviewed and updated to ensure it is current and effective in meeting employee needs. The Laboratory has reported to Fermi Site Office that from October 1, 2008 through September 30, 2009, 2,027 of the Laboratory's 2,122 employees (95.5%) had an ITNA performed for them. Of the 25,875 required ES&H courses, 24,763 (95.7%) have been completed thus far this FY, and that the bulk of the non-completed classes are those that are required before access is allowed into the accelerator tunnel or enclosures. Finally, training is reviewed by the Subject Matter Expert (SME) during audits as well as during FESHM updates, subcommittees of the Laboratory Safety Committee frequently review training as part of doing business, feedback from the classroom evaluation forms is used to improve training materials, and recent reorganization in ESHS has led to a review of both the ITNA and the training materials as they were migrated from the server to DocDB.

During interviews with the Accelerator Division (AD) it was learned they were piloting the use of an iPod Touch as a training aid for their operators. This innovative pilot provides videos that can be viewed in the field to walk operators through procedures. AD employees have produced nineteen (19) such videos.

Individual employee job qualification requirements are established through the job description prepared for a position. During the hiring process individuals satisfying recognized qualifications are sought out to fill specified job needs. As duties and responsibilities are modified, so might job qualification requirements. All job descriptions are reviewed on a 5 year cycle to ensure they remain current.

Conclusion:

Fermilab possesses an existing training and qualification management system to establish individual employee needs, and to track training scheduling and completion. Though this system was originally intended for ES&H, and still mostly serves the Laboratory in that capacity, its use is gradually expanding into monitoring the training and qualifications established for other Laboratory management systems. The Laboratory has identified inconsistencies with organizational assignments and responsibilities shown in the Director's Policy for training and qualification. Corrective action plans have been established to address those inconsistencies.

Strength:

- The AD's use of an iPod Touch as a video training aid is an innovative approach for walking operators through procedures in the field.

CRITERION 3 - QUALITY IMPROVEMENT

Discussion:

The Fermilab IQA document describes the approach and roles and responsibilities for Quality Improvement at Fermi. The IQA implementation emphasis is on integration into the planning process of the results of assessments and identification of problems or areas where improvements can be gained, as well as corrective action implementation and verification. Review of documents and discussions with line organizations, consistently produced examples of improvements gained in a number of different ways. Many divisions, most notably CD and PPD, use performance metrics and trending to identify problems and or areas where improvements can be realized. PPD has an active quality control program for experimental components built in house or purchased from vendors, and uses the results of their QC efforts to improve component specifications, systems and products. Such examples of quality improvements were well documented for the Minerva and Minos projects.

CD's pursuit of ISO 20000 *Information Technology Service Management* certification for information technology (IT) management service demonstrates a commitment to quality improvement. The scope of the standard addresses management system requirements for delivery and control of IT services. CD is implementing the requirements of the ISO standard in a number of phases over the next couple of years. One of the phases that has been completed is the *Problem Management Process and Procedure*, which provides an effective mechanism for the identification, analysis, and resolution of problems. Performance issues and interruptions are trended and analysis of these trends is used to identify improvements to systems and services. The *Problem Management Process and Procedure* also requires causal analysis to be performed for issues of significant risk.

CD has established several performance indicators. CD data centers have interactive machine uptime and performance quality statistics. CD monitors and trends issues from IT service tickets. As a result of its pursuit of ISO 20000 certification, CD is working toward a comprehensive management process that integrates process performance indicators and trending to drive continuous improvement.

Other organizations such as TD, BSS and WRDS rely on staff observations/suggestions, management reviews, customer feedback and/or assessments and external reviews to identify areas for improvements. The TD 2010 *Quality Management Program* is a mature, well documented and effective quality improvement program. Employees are encouraged to make suggestions and required to report deficiencies. Quality Control Reports (QCRs) and Discrepancy Reports (DRs) are used to document and resolve deviations from specifications or processes within TD and by vendors. TD expects workers to routinely compare the processes and products to expectations to ensure effective product delivery. TD is clear in its expectations that employees closest to daily operations are in the best position to understand deficiencies, provide feedback on them, and make recommendations for improvement.

PPD's use of Operational Readiness Clearance (ORCs) as part of the work authorization process has resulted in improvement, most notably in the ES&H.

WDRS does course evaluations after each training class to verify quality of the instructor and the course content. These reviews are shared with the instructor. All organizations interviewed emphasized that they place a significant amount of effort in training as a means of ensuring quality. WDRS conducts monthly HR Process Improvement meetings.

The ES&H program is also assessed annually by ISO certifying bodies to maintain their certifications to ISO 14001:2004 *Environmental Management Systems*, and OHSAS 18001:2007 *Occupational Health and Safety Management Systems*. These annual external

assessments help to drive the pursuit of improvements in achieving environmental goals and overall ES&H performance.

Brochures, postings and newsletters are used to provide information on worker feedback. Although there is no formal document describing a Laboratory worker feedback program, worker feedback is encouraged and examples were given where worker feedback resulted in improvements.

Event reporting is adequately covered in various chapters of the Fermi Environment Safety and Health Manual (FESHM), specifically, FESHM 3010 Significant & Reportable Occurrences, FESHM 3020 Incident Investigation & Analysis, and FESHM 3030 Noncompliance Tracking System.

A formal institutional Lessons Learned program is still being developed and is addressed in the elevated CAP OQ-05-30-2009-3 (Lessons Learned). OQBP is working with ES&H to expand upon the existing Lessons Learned program documented on the ES&H Section web-site.

Lessons learned are routinely used in PPD and TD in the areas of work planning and hazard analysis and for projects and experiments. PPD had a significant number of lessons learned utilized in the areas of ES&H and projects. Organizations were able to give examples in which information from inside the Laboratory as well as external sources were used in work planning or in improvements to existing work processes. Sharing of lessons learned generated by Fermilab with the rest of the DOE complex was not as pervasive.

PPD and ES&H, primarily their QARs and/or ES&H Coordinators, subscribe to and review the DOE LL and ORPs databases. The PPD website includes links to lessons learned sources, ORPS reports, etc.

Incidents are reported at the weekly Scheduling Meeting held by the ES&HS and the Director with all Division Heads. Fermilab has an Injury/Illness Prevention Subcommittee, made up of Senior Safety Officers (SSOs) and medical staff, that reviews injuries around the Laboratory to seek better ways to prevent injuries. There are also the SSO meetings, where SSO's gather to discuss other safety issues in their divisions. JHAs, ORCs, ESH presentations at division monthly meetings provide lessons learned feedback. ES&H section distributes LLs and ORPs and associated information to the SSOs for distribution to the staff.

The IQA describes expectations for the issues management process at Fermi in the *Quality Improvement* Chapter. Section 3.3.3, *Quality Problem Resolution Analysis* and Section 3.3.4, *Root Cause Assessment and Corrective Action* lists the necessary elements of issue evaluation and extent of condition, cause determination, corrective actions, verification and effectiveness reviews.

The description and elements referenced in the IQA are consistent with the language in Chapter 9 of the Fermilab Integrated Contractor Assurance Program (FICAP). Implementing procedures that establish an integrated approach for issues management at Fermi are still being developed and are addressed in an elevated CAP. Specifically, the Laboratory needs to develop a procedure for conducting causal analysis that provides clear direction to line organizations on the level of effort, rigor, and type of causal analysis required. This should be addressed by CAP OQ-05-30-2009-5 Root Cause.

Causal analysis is conducted by many of the organizations at Fermilab, however, the level of rigor, formality, and documentation varies significantly from organization to organization.

The Fermilab *Corrective and Preventive Action Procedure*, 1004.100, identifies responsibilities and provides direction and expectation for developing corrective actions. Some weaknesses in the procedure were noted. The term *nonconformities* is used without

being clearly defined (a definition is included in the IQA document but for clarity the definition should also be included in this document to assure consistent application). The procedure uses general terms such as *complex*, *simple,* and *high risk* without clearly defining them. This situation occurs in related documents also (i.e., IQA, FICAP, draft *Management Assessment* procedure, *Corrective & Preventive Action* procedures), where terms used to characterize or categorize problems are not consistently used in the body of the document. Also, the criteria for determining the need for a *complex* versus *simple* root cause analysis, contained in the Appendix of the Fermilab *Corrective and Preventive Action Procedure,* lacks sufficient direction for consistent application.

Issues and problems are tracked in a number of ways. Institutional issues managed by the Assurance Council and OQBP were identified in the "As-Is" Process and are tracked. Fermilab tracks ES&H issues and actions in ESHTRK. Concerns regarding the effectiveness of ESHTRK had been identified by previous FSO oversight; resolution is occurring in relation to that previous oversight.

There is a strong Laboratory-wide effort to reduce the number of open corrective actions. The QA awareness throughout the Laboratory has improved as a result of the "As-Is" assessment and the communication efforts of the Laboratory Director to improve awareness of QA requirements and their importance.

Conclusion:

The quality improvement portion of the Fermilab IQA should satisfy the DOE QA requirements upon full implementation as described in the IQA program documents. Many strong quality improvement activities are already being implemented in various parts of the Laboratory.

Event reporting is adequately covered in various chapters of the FESHM. A formal institutional lesson learned program is still being developed and is addressed in the elevated CAP OQ-05-30-2009-3 Lessons Learned. The IQA requires line organizations to track their quality problems and corrective action. Issues and problems are tracked in a number of ways with varying levels of detail and documentation.

Strength:

- CD's pursuit of certification to ISO 20000, *Information Technology Service Management* for IT service demonstrates a commitment to quality improvement. CD is implementing the requirements of the ISO standard in a number of phases over the next couple of years. One phase that has been completed and is already a success is the CD *Problem Management Process and Procedure*, which provides an effective mechanism for the identification, analysis, and resolution of problems. Performance issues and interruptions are trended and analysis of those trends is used in identifying improvements to systems and services.

Concerns:

- The term *nonconformities* is used without being clearly defined in the *Corrective and Preventative Action Procedure*. Also, the procedure uses general terms such as *complex*, *simple,* and *high risk* without clearly defining them.
- The criteria for determining the need for a *simple* versus *complex* root cause analysis, contained in the Appendix of the Fermilab *Corrective and Preventive Action Procedure,* lacks sufficient direction for consistent application. (It is noted that the *Root Cause Procedure* is still in development.)

CRITERION 4 - DOCUMENTS AND RECORDS

Discussion:

Laboratory requirements for Document Control flow down from the Director's Policy Manual, No. 13, delegating the control to the issuing organization. Minimum requirements are specified, such as a Document Number, Revision, Issue and Date in the heading. Reviews and review frequency are determined by the issuing organization.

The Fermilab IQA program document describes why documents need controls, "to ensure that the direction they provide is accurate, current, and approved by authorized individuals," and describes how Fermilab documents comply with the DOE directive. Responsibilities are assigned to all levels of staff members.

There are some very good examples of effective Document Control within many of the D/S/C, however, there are numerous inconsistencies which detract from overall cohesive implementation across the Laboratory. For example, some procedures are not in a current review cycle, or a review cycle has not been determined. The ongoing use, or disregard, of potentially out-dated procedures shows reliance on experts and not on a documented system of procedures. Procedures that clearly document processes and that are used, followed, and maintained provide the internal controls that help assure consistency of process implementation and work quality. There are also other contributors for process effectiveness in addition to procedures, such as a robust training program and well-developed training materials that can assure that personnel have sufficient competence to perform their assigned duties.

Procedures are controlled in a wide variety of methods, from D/S/C websites with a software product called DocDB, others in electronic databases. Generally, paper copies are uncontrolled, forcing the user to search and to validate that their procedure copy is current prior to use. Only one Division produced a list of all controlled documents – other Divisions pointed to the websites as the list. So the document collection, while stored together, may not adequately provide controlled documents (training, procedures, or user guides) for all required work processes.

Some document control CAPs were kept within the D/S/C for actions, e.g., creating a mechanism for version control of the D/S/C procedures or creating new documented procedures where none or only informal guidance was in use. The decisions in document control elevated to the OQBP CAP were those with respect to the required header/footer information, to make all Fermilab documents more consistent, and whether a Laboratory-wide solution would be researched and implemented for document accessibility, e.g., SharePoint software.

The Fermilab IQA program document describes the importance of records as "...necessary to provide evidence of process effectiveness and conformity with requirements," and describes how Fermilab records comply with the DOE directive. Responsibilities are again assigned to all levels of staff members.

A Director's Policy for Records Management is currently in draft. Additionally, a Records Management Handbook has been drafted, which just recently entered the final review process. These documents, the Directors Policy and the Records Management handbook, when finalized, will provide improved records management guidance to both records generators and managers across the Fermilab D/S/Cs. As a remedial effort while these draft documents are being finalized, the D/S/Cs are utilizing the existing BSS Records Management Procedure.

Records Management staffing is comprised of a Records Manager within the BSS, the assigned D/S/C Records Coordinators and administrative staff assigned as File Custodians.

Recent assessments have already recognized document control and records management deficiencies. There were 12 findings from the 2006 QA Assessment in this area. Of these, two remain open with corrective actions in process. In the most recent "As-Is" self-assessment, there were found to be inconsistent controls and 50% of the corrective action plans (CAPs) were in this area. These consisted of issues in differing kinds and levels of controls, insufficient requirements awareness, and flowdown issues.

Several of the document control and records management CAPs were elevated to the OQBP to evaluate the need for a Laboratory-wide solution, rather than establishing the requirements within the D/S/C. Because of this, some D/S/C personnel expressed a hesitancy to move forward with the D/S/C-level improvements/solutions, since Laboratory-wide processes may be established that contradict their initial direction. The OQBP didn't disagree with that approach, and confirmed that it was appropriate for the D/S/C to be awaiting OQBP actions.

Some records management CAPs were kept within the D/S/C for actions, e.g., creating a file plan for records using DOE-approved retention schedules. In the records management area, there were many facets identified for improvement, within the D/S/C, including increasing awareness of D/S/C staff members on what constituted a record, and needed to be maintained, creating file plans with retention schedules for both paper and electronic records. The Records Management Program documents and resources improvements were assigned to the BSS. There are ongoing improvements to the Records Management Program documentation, and on-site visits by the BSS Records Administrator, were initiated to provide awareness and training to the individual D/S/C staff, including Records Coordinators and File Custodians. The BSS Records Manager had visited the D/S/C to personally guide awareness and improvements. Additionally the Records Manager is made aware of staff departures and any records left behind are reviewed to determine their disposition.

Conclusion:

The Laboratory has identified, and is working to correct, deficiencies in both Document Control and Records Management. While there is solid evidence of established document control and records management within many D/S/C, a number of corrective actions identified areas for improvement. Some of the deficiencies may require a Laboratory-wide implemented solution as the most cost-effective solution, and those are under evaluation.

CRITERION 5 - WORK PROCESSES

Discussion:

Work processes at Fermilab encompass the design, operation, maintenance, modification and construction of experiments, accelerators, systems, and procedures. There are also numerous work processes in the business support and facility operations functions, e.g., hiring, training and performance monitoring of staff in the human resources arena; business functions such as procurement, finance, budget, records management, property management, shipment/receipt of materials, and the management and maintenance of buildings and grounds.

There is a recently-issued Director's Policy No. 42, *Scientific Research,* which states that research activities are to be conducted to the highest scientific and ethical standards and the research activities must comply with all local, state, and federal regulations and DOE requirements that address the protection of the environment, public, and personnel. The actual operation of experiments and basic research is covered under a separately identified "Scientific Research" work process within the Fermilab IQA program document. Scientific

research is performed in accordance with generally accepted scientific methods and controlled by scientific collaboration, publication in peer reviewed journals and review by DOE.

The Fermilab IQA Chapter 11 establishes the QA expectations for Scientific Research. Two additional referenced documents further describe QA program implementation and procedures for scientific research: (1) *Quality Assurance Guidelines for Scientific Research at Fermilab* describes how Fermilab has adopted the standard ANSI/ASQ Z1.13-1999 *Quality Guidelines for Research*; and (2) *Procedures for Experimenters* (PFX). For the scientific research work process, the desired and planned end result is valid scientific research and successful collaboration for the conduct of basic research at the frontiers of elementary particle physics and related disciplines.

The QA Guidelines for Scientific Research at Fermilab provides researchers with specific guidance on the management, planning, performing, documenting, assessing the performance, and the transferring the results of research. Depending on the process step and research type (theory, experiments, tests or technology R&D), there are required reviewers established (at Table I) to include appropriate reviewers from the top line management to the individual researcher and peers within the organization. This includes reviews, where appropriate, by the assigned level of line management, including the Fermilab Director and Deputy Director, Associate Director, D/S/C Head, Department Head, Group Leader, Spokesperson, Principal Investigator, or Experiment-Based Review Body, Individual Researcher or Research Team, and the Publication Editor/Peer Review process.

ES&H requirements and controls for work process hazards are well defined in the FESHM; e.g., FESHM Chapter 2060, *Work Planning and Hazard Analysis*, FESHM Chapter 10010, *Radiation Safety Program*, FESHM Chapter 6010, *Elements of the Fire Protection Program* and FESHM Chapter 5101, *Personal Protective Equipment (PPE)*. ES&H staff training for work hazards awareness is well-established and is described under Criterion 2- Personnel Training & Qualification of the Fermilab IQA.

The "List B" of the M&O contract in place at Fermilab contains a mix of Federal Regulations (CFR), DOE directives, and national/international consensus standards (ASME, IAC, ANSI, ASME, and NFPA). The Fermilab M&O contract also contains a set of Work Smart Standards (WSS). As new regulations are created, Fermilab and FSO review them for contract inclusion. Revisions to these requirements lists are incorporated through the issuance of contract modifications. The WSS is published in FESHM Chapter 1070, and was last published in 10/2007. The Fermilab Chief Operating Officer submitted proposed changes to the WSS set by letter dated 6/18/2008; it recommended the addition of an NFPA Standard, the replacement of an existing standard with its new revision, and the inclusion of a new Executive Order (EO) which cancelled and replaced three previous EOs. FSO provided concurrence with the proposed updates of the WSS set in a letter to the Laboratory dated 7/03/2008. In 10/2008, the OQBP forwarded an updated version of the WSS set to FSO. The 2008 WSS list and the official 2007 FESHM 1070 list differ by three regulations. There appears to be some confusion on the roles and responsibilities related to the maintenance of the "official WSS set" with the introduction of the OQBP role. The FESHM chapter is very specific on the process of updating, routing to FSO, then getting FSO approvals for changes then distribution to the Library and the FESHM chapter. It does not appear that the process to update the WSS set followed through to the end of the approval process.

Fermilab utilizes a graded approach to determine the level of controls applied to work processes performed at Fermilab. Controls applied to work processes include written procedures, performance monitoring and personal accountability. The supporting work processes follow the criterion in DOE O 414.1C. The graded approach process is intended

to identify activities which present significant quality risk, determine the risks and necessary controls, and document the determination. The *Fermilab Graded Approach Procedure*, procedure number 1002.1000, guides the selection of controls to be applied to activities which pose the greatest risk for significant negative impact on quality. This focuses attention on activities which require the most control and oversight, and reduces costs by minimizing the application of controls in areas of low risk.

There are selection criteria which identify those activities that present significant quality risk. When an item or service is deliverable to an outside organization, the evaluation is performed from the client's point of view. Activities which meet any of these criteria are required to go through the graded approach process. Activities which do not satisfy the selection criteria must still conform to standard laboratory-wide quality controls.

The following selection criteria are used:

- Major processes identified on lists of processes defined by each laboratory organization
- Reasonable likelihood of a 3 month delay (or 2 months for projects with duration less than 9 months) of the laboratory schedule
- Total project cost greater than $500K
- Reasonable likelihood of an occurrence, or repetitive occurrences, with cost impact greater than $100K
- Safety or environmental hazards, liabilities or risks greater than those generally accepted in an industrial environment
- Reasonable likelihood of a significant reduction in the public trust or scientific reputation
- Judgment of line management

Line management is responsible for applying the graded approach to determine the appropriate level of work process controls, including which activities require written procedures and which procedures are to be augmented through the appropriate personnel training and qualifications.

The graded approach procedure is in the process of being converted to a software tool; this may enhance the consistency of application of the grading criteria throughout the Laboratory.

This graded approach procedure was used in a very large effort led by the Fermilab OQBP with the D/S/C QARs and additional QAE support from January – July 2009 to determine a baseline for QA program compliance. Denoted the "As-Is" process, within each D/S/C, a list was created for their work processes, and using the selection criteria, with particular focus on "judgment of line management" (i.e., what keeps you up at night) selected major processes were chosen for evaluation. The evaluation generated approximately 100 Corrective Action Plans where gaps were identified in adequately meeting the DOE O 414.1C criteria. Some were elevated for consideration of laboratory-wide solutions, as has already been mentioned in this report. The "As-Is" efforts provided an excellent baseline for cross-walking Fermilab processes to the established DOE O 414.1C requirements.

The Fermilab organizations sampled in this assessment (AD, BSS, CD, ES&H, FESS, PPD, TD, WDRS) have processes to control items, and to properly maintain items and prevent their damage, loss or deterioration. TD, AD, BSS, FESS have a database of parts and equipment to support the management and storage of items. The AD Mechanical Group has a database of parts and equipment to note location and status.

TD has local procedures to control and store items. They have fire rated cabinets for flammables, and a cold storage room. Their storage area is locked. TD stockroom staff delivers items to TD groups as requested.

BSS manages and maintains laboratory stores. Storerooms and warehouses are access controlled. BSS has a sensitive and hazardous materials list which requires further review by specified persons before certain items can be procured and used. BSS controls the Fermilab program which uses credit cards for purchases, called "Pro Cards." Extensive training for users of these Pro Cards is required and sensitive and hazardous items cannot be purchased with the Pro Cards.

FESS Operations manages a storeroom for their shops. They perform inventory counts, and have appropriate storage facilities for the 10,000+ items they stock. FESS Operations is the lab custodian for refrigerant. There is a procedure that controls this function.

The ESH representative in PPD reviews the preliminary hazard assessment for experiments to understand the material and equipment needs of the experiment and ensure those materials are available and controlled, stored, and used properly. The ESH representative in PPD approves all PPD requisitions for chemicals; he and his staff work with PPD staff on the proper storage of chemicals in the division. PPD serves as the custodian for beryllium and lead for the entire Laboratory. These items are maintained in locked storage.

PPD has recently issued a calibration policy applicable to the entire Division. Items critical to project (research success) are tested to assure their performance levels meet specifications. The NOvA project QAP describes approaches for addressing the M&TE calibration criteria. Detailed procedures are being drafted as the program moves into the construction phase.

FESS Operations Group has procedures for calibrating the two pieces of equipment that require calibration. AD is drafting a calibration policy. The AD Mechanical Group is planning to create a calibration policy/procedure tailored to their operations. ES&H Division has a well-documented process for calibrating equipment used in worker safety. They maintain a calibration facility that has documented procedures for calibration of equipment.

Conclusion:

Work processes at Fermilab encompass the design, operation, maintenance, modification and construction of experiments, accelerators, systems, and procedures. There are also numerous work processes in the business support and facility operations functions; e.g., hiring, training and performance monitoring of staff in the human resources arena, and business functions such as procurement, finance, budget, records management, property management, shipment/receipt of materials, and the management and maintenance of buildings and grounds.

The desired end result of the scientific research work process is valid scientific research and successful collaboration for the conduct of basic research at the frontiers of elementary particle physics and related disciplines. Fermilab applies QA requirements to scientific research through the Director's Policy No. 42, *Scientific Research*, the *Fermilab Quality Assurance Guidelines for Scientific Research*, and Chapter 11 *Scientific Research* of the IQA. These documents implement the requirements of the national consensus standard ANSI/ASQ Z1.13-1999, *Quality Guidelines for Research*.

Fermilab organizations have processes to control items to ensure their proper use, and to properly maintain items and prevent their damage, loss or deterioration.

Fermilab organizations have processes to maintain and calibrate measuring and testing instruments.

Concern:

- There appears to be some confusion regarding the roles and responsibilities related to the maintenance of the official WSS set, as evidenced by the processing of the 2008 version of the Fermilab WSS set.

CRITERION 6 - DESIGN

Discussion:

The design of structures, systems, and components at Fermilab is performed using standard engineering techniques. Requirements typically are identified through customer/engineer dialogs and incorporated into the design. Interfaces are controlled via drawings. Designs are verified and validated through design reviews, which typically include the customer. These reviews help assure that customer requirements are properly incorporated in the design. Based on the results of these reviews, the approval to continue implementation of the design process is given.

It was found that the implementation for these approaches differs from organization to organization. In some Divisions, such as FESS, a procedure, *Construction Document Review and Distribution Procedure*, defines the design process in appropriate detail, describing the techniques to be used and documentation to be generated. In other Divisions, such as AD, interaction between management and engineers is relied upon to assure that appropriate designs are achieved. AD's approach is an "expert based" versus a "process based" system.

The *Root Cause Analysis for the Large Hadron Collider Magnet System Failure* (RCA) has as the root cause statement "Fermilab engineering management controls do not include codified, standard design process requirements that include a systems integrated design, design review, and documentation recording and archiving process. Instead, Fermilab relies upon individual contributors to obtain review of design basis calculations and recognition of interface and integration requirements. In both instances, the lack of documentation and in-depth review resulted in critical design errors being missed until the components were tested *in situ* at CERN."

The RCA also states the following on page 7: "...Fermilab's most senior, knowledgeable personnel are of, or are approaching retirement age. Unfortunately, a knowledge database or engineering lessons learn program has never been created to pass on the information and basis for decisions and design to incoming physicists and engineers. This detracts from one of the key discriminators that Fermilab has today – being one of the most experienced designers and fabricators of large machines in the high energy physics community."

A draft *Engineering Manual* was presented to the assessment team. The team was told that the Manual is near final. After reviewing the RCA, the team does not believe that the draft manual addresses the concerns of the RCA report, nor the requirements of DOE O 414.1C criteria 5.a and 6. In general, the manual assumes an expert based vs. process based system (contrary to RCA). Examples supporting this are:

1. (page 8) Per the Manual, "Project and system managers assure that tasks are completed using good engineering and quality control methods." These methods are not defined except as examples in the appendix.
2. (Page 10) The Lead Engineer prepares the specification with the general elements listed, but there is no specified format. A standard format helps assure that all important data is included. "N/A" can be indicated for those items not applicable and indicates that the author considered these items.

3. (Page 17) The design process described in the manual does not include inputs and constraints as required by the Fermilab *Integrated Quality Assurance* document, 1001, in paragraph 6.3.2.
4. (Page 23) The Manual states that the project documentation for the review will, at a minimum, "include a meeting summary describing who attended the review and what issues they discussed." There is no defined method to assure that these issues are adequately tracked and resolved.
5. (Page 4) In the Purpose/Scope section, the Manual states "This document provides a reference for properly executing and documenting engineering projects at Fermilab." and therefore implies that the manual itself is just a reference, not a manual.

While the assessment team does not believe that the processes should be prescriptive, commonly performed functions within design should provide a consistent methodology for the function while allowing appropriate discretion on the part of the engineer and management. For instance, the process for design reviews should describe minimally, for each of the commonly held reviews, the intent of the review (questions to be answered), the documentation to be generated, and the method by which issues are documented and tracked to resolution. The Fermilab *Engineering Manual* must appropriately balance, and therefore benefit from the strengths of, the Laboratory's strong scientific and engineering expertise, and a more formal process-based approach to the engineering design process.

In addition, the examples provided in the appendices to the Manual are primarily taken from the AD. While these are good examples, to assure that the Manual has the necessary buy-in across the entire Laboratory, a broad base of examples from all the Fermilab D/S/Cs should be included.

The *Integrated Quality Assurance* document, Chapter Six *Design*, indicates that the Laboratory will staff the position of Fermilab Chief Engineer, however interviews indicated that the decision to create and fill such a position has not been finalized.

Conclusion:

On the whole, Fermilab appears to perform good designs. Sometimes this is due to the processes established within an organization, sometimes to the interactions between management and engineers, and sometimes a combination of both. The system depends upon the knowledge of the engineering staff, which appears to be highly experienced and competent. However, the informality of the processes can present a risk, especially when the aging of the staff is taken into consideration. This was recognized by the Laboratory in the findings and recommendations of their *Root Cause Analysis for the Large Hadron Collider Magnet System Failure*. Fermilab should develop and implement a documented design control process that implements the recommendations of that report.

Strength:

- The experience level of the Fermilab engineering design staff is very high.

Concerns:

- Design processes in the laboratory are not consistent. In some areas of Fermilab design work at Fermilab is dependent on the experience of the staff and management/engineer interactions while in others, such as FESS, the process is well defined.
- The decision to create and staff the position of Chief Engineer has not been finalized.

Significant Concern:

- The draft Fermilab *Engineering Manual*, revision 0.2, does not provide sufficient detail and rigor to effectively implement the requirements of Criterion 6 *Design* and Criterion 5.a *Work Processes* of DOE O 414.1C *Quality Assurance*, and Chapter Six *Design* and Section 5.3 *Work Process Control* of the Fermilab *Integrated Quality Assurance* program, or to adequately address the inadequacies identified in the Fermilab *Root Cause Analysis for the Large Hadron Collider Magnet System* report. The Fermilab *Engineering Manual* must appropriately balance, and therefore benefit from the strengths of, the Laboratory's strong scientific and engineering expertise, and a more formal process-based approach to the engineering design process.

CRITERION 7 - PROCUREMENT

Discussion:

A graded approach is used for procurements, based on the monetary value of the item or service, as discussed in Section 6 of the Director's Policy Manual, and in the Procurement Policy and Procedures Manual. It is very clear who is authorized to obligate the Laboratory on a contractual basis. A letter from the Laboratory Director, titled "Procurement of Goods and Services" dated September 12, 2005, delineates procurement signature authority.

A total of 10 procurement packages were reviewed as part of this assessment (refer to the Documents and Records Reviewed section of this report). Specifications were included and any QA requirements noted; no issues were discovered during the review of these packages.

The use of the ProCard is a time and money saver for the laboratory. These are credit cards that one or two people in each group control. There is a $2500 limit for each use and clear direction exists as to what purchases that are allowed or are not allowed. These are typically used for commercial, off-the-shelf goods.

A Requisitioner is the ultimate user of an item or service, who creates a requisition and supplies any necessary documents such as prints and specifications. The QA requirements and deliverables, as necessary, are listed in the requisition. The Requisitioners work with the QARs to develop the QA requirements. The next person in the process at the group level is the Requisition Preparer. This person enters the requisition into the Oracle web-based requisition system.

The next step in the Procurement system is for the requisition to be assigned by Procurement management to a Procurement Administrator, a.k.a. the Buyer. This person is assigned to a particular requisition because of their experience with similar items and the vendors who can conceivably provide that item. The Buyer issues a Request for Quote (RFQ) or a Request for Proposal (RFP), depending on the circumstances. The Buyer's knowledge allows them to determine which vendors to send the RFP or RFQ to, based on past performance history. An "Approved Suppliers List" is not maintained because of the extensive experience of the Buyers.

Conversations may occur between the Requisitioner and vendor after the contract is let, although the Laboratory is trying to reduce the frequency of such occurrences. All those that were interviewed say that some of this necessary due to the technical nature of the procurements, and that they know they cannot obligate the laboratory through these conversations, but must involve the Buyer to help with any purchase order or contact revisions. If the technical conversation leads to the need to make a formal change to the contract, a Change Requisition is created by the Requisitioner in the Oracle system and then is processed as a Change Order by Procurement.

A particular strength of the procurement process is that often a Requisitioner works with the procurement group to develop and send to each potential vendor, a technical questionnaire that the vendor must complete. Another approach is to ask the potential vendor to create a prototype of the item for submission. Both of these methods allow the Requisitioner to judge whether the vendor has the technical qualifications to competently supply the item, and allow for eliminating from the bid process those who are deemed not to posses the necessary capabilities. In addition to the technical capabilities, the vendor is judged on their ability to meet project schedule requirements.

The Requisitioner is the individual who will receive the deliverables of the purchase order, and to determine their acceptability. It is the responsibility of the Requisitioner to notify the Procurement group when items arrive or services are performed, and if the buying

organization is satisfied with same. This is the final step that allows the Procurement group to close purchase orders. Depending on the characteristics of the item(s) being procured, inspection/testing is sometimes done at the vendor's site, prior to shipment to Fermilab.

Fermilab has an approved Fermilab Procurement Policy and Procedures Manual, dated December 22. 2003, that is currently undergoing a revision under CAP 1004.1001, Rev 000 C3. The Purchasing System was approved by the FSO in September 2008. Discussions with the FSO Business and Contract Support staff, and the Fermilab Procurement Manager confirmed that the procurement system complies with all applicable DOE Orders, the DEAR, and the FAR. All persons interviewed were satisfied with the system in place and were complimentary of the individuals who performed the required work in their groups and in the procurement office.

Conclusion:

The procurement system at Fermilab is mature, well documented, effectively implemented, and satisfies the Department's procurement QA requirements.

Strength:

- Potential vendors/suppliers of complex items are often requested to complete a Technical Questionnaire, or submit a prototype, to demonstrate the company's technical knowledge and capability.

CRITERION 8 - INSPECTION AND ACCEPTANCE TESTING

Discussion:

Engineers in CD, TD, AD, ES&H, and PPD write the inspection, test, and acceptance procedures for critical items. BSS performs a cursory inspection in order to receive items into the system before distributing it to the requesting D/S/C. Engineers in the D/S/Cs maintain the inspection and test records. The level of documentation of acceptance testing varies between the various Fermilab organizations.

In TD the inspection and test records are also kept in the acquisition group, with the acquisition records for that part. TD has an inspection and test group and calibration procedure for the M&TE used by that group. They have a database that tracks when M&TE is due for calibration. M&TE have calibration stickers on the instrument.

In PPD the NOvA project QAP describes approaches for inspection and acceptance testing. Detailed procedures are being drafted as the program moves into the construction phase.

The AD Mechanical Group incorporates test plans into work procedures.

The ES&H Division inspects and accepts waste drums for hazardous materials using a documented checklist that contains an appropriate level of detail.

Conclusion:

In each of the Fermilab organizations reviewed, there are processes in place for adequate fulfillment of the inspection and acceptance testing requirements. The level of documentation of acceptance testing varies between the various Fermilab D/S/Cs.

Strength:

- Strong programs for inspection and acceptance testing of procured items were observed at the TD and the PPD NOvA Project.

Concern:

- The level of documentation of acceptance testing varies between the various Fermilab D/S/Cs.

CRITERION 9 - MANAGEMENT ASSESSMENT

Discussion:

The IQA and FICAP define the assessment program and the management and organizational roles, responsibilities, and institutional expectations for the program. The IQA, FICAP and the draft *Assessment Manual* provide Fermilab with a defined structure to assessments. The assessment program at Fermilab is comprised of independent assessments conducted by OQBP, management review, and management assessment. Management assessments are those assessments conducted by line organizations.

However, the Fermilab assessment program has not been fully implemented. Two key procedures are still in draft: *Fermilab Management Assessment Procedure* and the *Assessment Manual.* These draft procedures will be key components of an effective assessment program.

Some strengths of the overall assessment program as described in the IQA and FICAP are the OQBP responsibilities to:

- monitor the adequacy and quality of assessments,
- perform oversight of the Contractor Assurance System, which includes the approval of audit plans,
- development and maintenance of an integrated assessment schedule, and
- monitor the status of corrective actions.

The central authority of OQBP for developing a Fermilab consolidated assessment schedule should provide a mechanism to ensure adequate use of resources by reducing redundant assessments while assuring mission, program and high risk activities and functions are covered.

An additional strength of the way the Laboratory's assessment program is being structured is the requirements and direction given in the draft Fermilab *Assessment Manual* which requires Management System Owners and D/S/C management to verify closure and validate effectiveness of corrective actions.

However, some weaknesses in the draft Fermilab *Management Assessment Procedure* were noted during this assessment. The procedure does not require the identification of the assessment criteria, or provide direction or guidance on how to scope assessments. This is important direction to give line organization to assure the assessment is not too broadly scoped to assure resources can adequately cover the topic in a reasonable time and with sufficient depth and rigor to add value. Some terms such as, *minor findings, significant findings, special assessments, Fermilab Director's Assessments,* and *third party assessments* are not sufficiently defined to allow for consistent application. In addition, some terms in the *Definitions* section that are useful for characterizing the significance of assessment issues are not used in the body of the document nor in other documents germane to assessments (IQA, FICAP, draft *Management Assessment* and *Corrective & Preventive Action* procedures).

All organizations assess their performance against contract measures and other performance criteria. Currently however, the only self-assessments and management

assessments done routinely across the Fermilab D/S/Cs are those related to ES&H. Some organizations such as CD and TD have formal management assessments and self-assessments. TD has a mature and effective program. PPD's project reviews and ORC's provide effective assessments.

CD has established a three year assessment cycle for their management/self-assessments. CD staff members are aware of the importance of self-assessments, and CD management encourages critical appraisals as evidenced by their decision to pursue ISO 20000 certification.

During the "As-Is" assessment process, PPD identified that a QA assessment program was not being implemented, and is currently working on development of a self-assessment procedure modeled on PPD's mature ES&H assessment program. This new Quality Assessment Procedure would then integrate the ES&H assessment procedure into the new QA assessment procedure and therefore eliminate the need for two assessment procedures.

Conclusion:

The IQA and FICAP define the assessment program and the management and organizational roles, responsibilities, and institutional expectations for the program. The IQA, FICAP and the draft *Assessment Manual* provide Fermilab with a defined structure to assessments. The assessment program at Fermilab is comprised of independent assessments conducted by OQBP, management review, and management assessment. However, the Fermilab assessment program has not been fully implemented. Two key documents are still in draft: *Fermilab Management Assessment Procedure* and the *Assessment Manual.*

Strengths:

- The OQBP responsibilities to monitor the adequacy and quality assessments, provide oversight of the Contractor Assurance System, approve audit plans, and monitor the status of corrective actions should enhance the effectiveness of the Fermilab assessment program.
- The role of OQBP in developing a consolidated Fermilab assessment schedule should provide a mechanism to ensure adequate use of resources by reducing redundant assessments while assuring mission, program and high risk activities and functions are covered.
- The direction given in the draft *Fermilab Assessment Manual* that requires Management System Owners and D/S/C management to verify closure and validate effectiveness of corrective actions should enhance the effectiveness of quality improvement and assessment activities.

Concerns:

- The draft *Fermilab Management Assessment Procedure* does not require identification of the assessment criteria, or provide direction/guidance on how to scope assessments. This is important direction to provide to line organizations to ensure assessment are not too broadly scoped for the available resources to adequately cover the topic in a reasonable time and with sufficient depth and rigor to add value.
- Some terms such as *minor findings, significant findings, special assessments, Fermilab Director's Assessments,* and *third party assessments* are not sufficiently defined to allow for consistent application. In addition, some terms in the *Definitions* Section that are useful for characterizing the significance of assessment issues are not used in the body

of the document or in other documents germane to assessments (i.e., IQA, FICAP, draft *Management Assessment Procedure* and *Corrective & Preventive Action Procedures*).

CRITERION 10 - INDEPENDENT ASSESSMENT

Discussion:

The IQA, FICAP and the draft *Fermilab Assessment Manual* provide the Laboratory with a defined structure to assessments. Independent assessments at Fermilab are audits conducted by FRA, and surveillances, assessments and inspections conducted or sponsored by OQBP. Management assessments are those assessments conducted by line organizations. Currently, internal independent assessments are primarily conducted as part of the work authorization process (Operational Readiness Clearance) and/or as project reviews. Internal independent assessments of line organizations have been conducted in the functional area of ES&H, and as a result of incidents.

External assessments are routine from DOE in the areas of ES&H and some of the business functions in BSS. In addition, peer reviews by outside institutions are fairly routine in WDRS. The ES&H program is also assessed annually by ISO certifying bodies to maintain their certifications to ISO 14001:2004 Environmental Management System, and OHSAS 18001:2007. External peer reviews of the laboratory's scientific research programs occur routinely.

The draft *Fermilab Assessment Manual* is structured to provide clear direction and guidance to OQBP for conducting independent assessments and to line organizations for planning and executing management assessments. The Manual's description of requirements for planning and executing independent assessments and other elements of the assessment program is thorough and well defined.

The draft *Assessment Manual* reflects the thought and effort put into the As-Is Process and the notable efforts of OQBP to institutionalize this successful effort. The *As-Is Process* provided significant value to the efforts to institute the IQA by:

- Establishing the base-line of the Laboratory's conformance with the requirements of the IQA and FICAP;
- Developing integrated CAPs for the institution and line organizations;
- Piloting a more formal and rigorous assessment and corrective action process with full participation of the line organizations.

Conclusion:

The draft *Fermilab Assessment Manual* provides clear direction and guidance on the conduct of independent assessments. The manual's description of requirements for the planning and execution of independent assessments and other elements of the assessment program is thorough and well defined.

Strengths:

- The Fermilab *As-Is Process* provided significant value by:
    - Establishing a base-line of the Laboratory's conformance with the requirements of the IQA and FICAP;
    - Developing integrated CAPs for the institution and line organizations;
    - Piloting a more formal and rigorous assessment and corrective action process with full participation of the line organizations.

- The maintenance of Fermilab's certifications to ISO 14001:2004 and OHSAS 18001:2007 requires independent assessment by external third party review teams.

SUSPECT/COUNTERFEIT ITEMS PREVENTION

Discussion:

Each of the Fermilab organizations included in this assessment were aware of what Suspect/Counterfeit Items (S/CI) are and why they need to be prevented from use; and all had S/CI Coordinators and a number of staff trained in S/CI. BSS/Procurement requires suppliers and distributors to certify the authenticity of the items they provide. Some D/S/C who work with small inventories of parts, or use special parts, while aware of S/CI are not as susceptible to S/CI at this time.

The Head of the Quality & Materials Group in TD keeps a file on S/CI found in TD. TD investigates incidences of S/CI and develops corrective actions. In TD S/CI materials are documented and dispositioned using a Discrepancy Report (DR) if found in existing equipment. S/CI materials found during TD acceptance testing are tracked on a Quality Control Report (QCR)

Information about S/CI events is disseminated by OQBP. S/CI issues are examined first to establish the accurate existence of a suspect or counterfeit item as opposed to an inadvertent nonconformance; the OQBP communicates with FSO when these issues exist and has a procedure to report them through the DOE ORP System when valid S/CI is found. The OQBP did an extensive amount of collaboration with other laboratories in developing its S/CI procedures, in order to focus on practical implementation rather than a procedure that exists but is not followed as written.

GIDEP is not used at this time but is being considered.

Some of the Fermilab line organizations were not sure of OQBP's role regarding S/CI. Many believe OQBP owns the Laboratory's S/CI process, but were not sure what exactly that means in terms of dealing with S/CI when found. The Fermilab S/CI program document is still in draft, which may contribute to this perception. TD, PPD, and AD each have a collection of S/CI in their facilities that they have identified and have segregated out of the workflow. They are holding these items until the Laboratory-wide S/CI program is "up and running", pending the release of the draft OQBP S/CI procedure. While segregated, having those S/CI out in the field may pose a vulnerability.

Conclusion:

Fermilab organizations are aware of S/CI concerns and risks, have trained staff in S/CI, and generally understand and follow the Laboratory's S/CI program.

Strength:

- A high degree of awareness exists within the Laboratory regarding the potential impact of S/CI. Extensive training has been provided to a wide selection of employees who may encounter S/CI in their work

Concerns:

- Some line organizations were not sure what role OQBP played in S/CI. They believe OQBP owns the Laboratory's process, but were not sure what exactly that means in terms of dealing with S/CI when found. The Laboratory's S/CI program document is still in draft, which may contribute to this perception.

- TD, PPD, and AD each have a collection of S/CI in their facilities that they have identified and have segregated out of the workflow. The perception is they are holding these items until the Laboratory-wide S/CI program is "up and running", pending the release of the draft OQBP S/CI Procedure. Having these S/CI out in the field poses a vulnerability.

Corrective Action Requirements:

Fermilab must provide FSO with their proposed resolution for each of the concerns identified in this assessment report. Fermilab must provide a Corrective Action Plan for the significant concern identified by this assessment, for approval by FSO. Prior to the resolutions and corrective action plan being finalized and signed-off by the Fermilab Director, FSO will meet with the Laboratory to review and discuss the proposed actions. The Laboratory's response is due to FSO within thirty (30) days of the issuance of the final assessment report.

Documents and Records Reviewed:

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- CD Strategic Plans, FY 2009
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Personnel Interviewed:

Laboratory Directorate	OQBP	ES&H
Oddone, Pier	Grant, Bob	Arnold, B.
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